Date of Approval Letter: NOV 2 4 2003

FREEDOM OF INFORMATION **SUMMARY**

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 140-841

IVOMEC (Ivermectin) Pour-On for Cattle

To add persistent effect periods for 3 additional parasite species and extend the period of persistent effect for 3 existing parasite species.

> Sponsored by: Merial Ltd.

1. GENERAL INFORMATION

A. File Number:

NADA 140-841

B. Sponsor:

Merial Ltd.

3239 Satellite Blvd., Bldg. 500

Duluth, GA 30096-4640

Drug Labeler Code: 050604

C. Established Name:

Ivermectin

D. Proprietary Name:

IVOMEC (ivermectin) Pour-On for Cattle

E. Dosage Form:

Topical solution

F. How Supplied:

250-mL, 1-liter, 2.5-liter, 5-liter, and 20-liter

containers

G. How Dispensed:

Over-the-Counter (OTC)

H. Amount of Active Ingredients:

5 mg ivermectin/mL

I. Route of Administration:

Topical application along the topline extending from

the withers to the tailhead

J. Species/Class:

Cattle

K. Recommended Dosage:

1 mL for each 22 pound body weight to provide 500

mcg ivermectin/kg body weight

L. Pharmacological Category:

Antiparasitic

M. Indications: For the effective treatment and control of these parasites.

Gastrointestinal Roundworms

Ostertagia ostertagi (adults and L₄)

(including inhibited stage)

Haemonchus placei (adults and L₄)
Trichostrongylus axei (adults and L₄)
T. colubriformis (adults and L₄)
Cooperia oncophora (adults and L₄)
Cooperia punctata (adults and L₄)
Cooperia surnabada (adults and L₄)

Strongyloides papillosus (adults)

Oesophagostomum radiatum (adults and L_4)

Trichuris spp.

(adults)

Lungworms

Dictyocaulus viviparus

Cattle Grubs

Hypoderma bovis

H. lineatum

Mites

Sarcoptes scabiei var. bovis

Lice

Linognathus vituli Haematopinus eurysternus Damalinia bovis Solenopotes capillatus

Horn Flies

Haematobia irritans

Persistent Activity

IVOMEC Pour-On has been proved to effectively control infections and protects cattle against reinfection with: *Dictyocaulus viviparus* and *Oesophagostomum radiatum* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *Ostertagia ostertagi, Haemonchus placei, Cooperia oncophora* and *Cooperia surnabada* for 14 days after treatment; *Damalinia bovis* for 56 days after treatment.

(adults and L_4)

(parasitic stages)

Treatment of Cattle for Horn Flies

IVOMEC Pour-On controls horn flies (Haematobia irritans) for up to 28 days after dosing.

n. Effect of Supplement:

To add the new persistent activity indications for Dictyocaulus viviparus for 28 days after treatment, Cooperia surnabada for 14 days after treatment, and Damalinia bovis for 56 days after treatment. To extend the persistent activity periods for Oesophagostomum radiatum from 14 to 28 days after treatment and Cooperia punctata and Trichostrongylus axei from 14 days to 21 days after treatment. At this time, the labeling is being revised to reflect updated environmental information, to speciate Cooperia spp in the treatment and control section of the indications, and to add the veal calf warning statement to the residue information section.

2. EFFECTIVENESS

A. Dose Characterization

Effectiveness studies were presented in the original NADA 140-841 FOI Summary dated December 7, 1990, establishing the recommended effective dose of IVOMEC Pour-On for the treatment and control of internal and external parasites.

B. Substantial Evidence for Persistent Effectiveness Against Endoparasites

Five pivotal studies were conducted in the United States to evaluate the persistent activity of IVOMEC Pour-On in preventing infection of treated cattle with third stage larvae of several species of endoparasites. The studies had similar designs with separate groups of cattle receiving a daily challenge of third-stage nematode larvae 15, 21, or 28 days following treatment with ivermectin administered in its final formulation at a dose level of 0.5 mg/kg body weight. The efficacy was determined by comparing the geometric mean worm counts of the treated groups with those of an untreated control group for each parasite species present in at least six adequately infected control animals. P-values were computed for each parasite species using contrasts in a one-way analysis of variance or unequal-variance t-tests on log-transformed counts. The period of persistent activity was defined as the time during which the efficacy against a genus species was ≥ 90%.

For an indication to be granted, a minimum of two studies showing 90% efficacy was required for each genus species of parasite and at each persistent effect period. The new indication of persistent effect against *Dictyocaulus viviparus* for 28 days after treatment is supported by Trial ASR 15090 and Trial ASR 15095. The new indication for persistent effect against *Cooperia surnabada* for 14 days after treatment is supported by Trial ASR 14553 and Trial ASR 15110. The extension of the persistent effect period for *Oesophagostomum radiatum* from 14 days to 28 days is supported by Trial ASR 15110 and Trial ASR 15111. The extension of the persistent effect period for *Cooperia punctata* from 14 days to 21 days is supported by Trial ASR 15110 and Trial ASR 15111. The extension of the persistent effect period for *Trichostrongylus axei* from 14 days to 21 days is supported by Trial ASR 15111. The five trials are individually summarized below.

B.1 Trial ASR 14553

1) Type of Study: Dose confirmation study in cattle with induced infections of gastrointestinal roundworms.

2) Investigator:

Bruce N. Kunkle, D.V.M., M.S., Ph.D.

Merial Limited Fulton, Missouri

3) General Design:

- a. Purpose: To determine the period after treatment during which infections of gastrointestinal roundworms are controlled.
- b. Animals: Twenty-eight (28) crossbred female and castrated male calves (7 per group), approximately 6 months old and weighing 152 to 221 kg at the start of the study were used. All animals were treated with another anthelmintic during the acclimation period to eliminate existing infections.
- c. Treatment Groups: There were 4 treatment groups. One group received IVOMEC Pour-On. The negative controls received no treatment. Two groups received medications which were not pertinent to this approval and are not reported.
- d. Infection: Infective larvae were given to each animal daily, starting on the day of treatment, according to the following schedule: *Cooperia* spp. (1000 per day for 15 days). There were larvae of other genus species given for various lengths of time that are not pertinent to this approval and are not reported. This study provided support for the 14-day persistent effect period, even though the larvae were administered for 15 days.
- e. Dosage Form: The dosage form was IVOMEC Pour-On topical solution, 5 mg ivermectin/mL.
- f. Route of Administration: Topical.
- g. Dose: 1 mL/10 kg body weight (500 mcg ivermectin/kg body weight) once.
- h. Test Duration: 49 to 51 days after treatment.
- i. Pertinent Variables Measured: Worm counts were determined at necropsy, 49 to 51 days after treatment, 35 to 37 days after the last *Cooperia* spp. larvae were administered.
- 4) Results: There was an adequate level of infection in at least 6 control animals for 3 species of *Cooperia*. Efficacy is summarized in Table 2.1:

Table 2.1 Trial ASR 14553 - Percent Efficacy IVOMEC Pour-On 15-day Persistent Effect Period

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	Geometric	Geometric	% Efficacy of
Nematode Species	Mean in	Mean in	IVOMEC
_	Controls	Treated	Pour-On
Cooperia oncophora	223.3	0.5	99.8
Cooperia punctata	2949.8	0.5	99.9
Cooperia surnabada	154.2	0.5	99.6

5) Adverse Reactions: Some animals had loose stools during the trial and one animal vomited. These problems were not believed to be related to the experimental treatments.

B.2 Trial ASR 15090

- 1) Type of Study: Dose confirmation study in cattle with induced infections of lungworms.
- 2) Investigator: Edward G. Johnson, D.V.M. Johnson Research

Parma, Idaho

- 3) General Design:
 - a. Purpose: To determine the period after treatment during which infections of lungworms are controlled.
 - b. Animals: Forty (40) Holstein intact male calves (10 per group), no more than 8 months old and weighing 183 to 278 kg at the start of the study were used. Animals were free of patent infections at the time of treatment.
 - c. Treatment Groups: There were 4 treatment groups. Two groups received IVOMEC Pour-On. Two groups were negative controls that received the vehicle for IVOMEC Pour-On topically at 1 mL/10 kg body weight.
 - d. Infection: Infective larvae were given to each animal daily, starting on the day after treatment, according to the following schedule: *Dictyocaulus viviparus* (50 per day for 21 or 28 days). There was a separate control and treated group for each time period.
 - e. Dosage Form: The dosage form was IVOMEC Pour-On topical solution, 5 mg ivermectin/mL.
 - f. Route of Administration: Topical.
 - g. Dose: 1 mL/10 kg body weight (500 mcg ivermectin/kg body weight) once.
 - h. Test Duration: 42 or 49 days after treatment.
 - i. Pertinent Variables Measured: Worm counts were determined at necropsy, 42 days after treatment for the 21 day period or 49 days after treatment for the 28 day period, 21 days after the last *Dictyocaulus viviparus* larvae were administered for each group.
- 4) Results: There was an adequate level of infection in at least 6 control animals for both time periods. Efficacy is summarized in Table 2.2:

Table 2.2 Trial ASR 15090 - Percent Efficacy IVOMEC Pour-On Against

Dictyocaulus viviparus

	Geometric	Geometric	% Efficacy of
Persistent Effect Period	Mean in	Mean in	IVOMEC
	Controls	Treated	Pour-On
21 days	34.5	0	100
28 days	23.3	0.1	99.4

5) Adverse Reactions: An injured left hind leg, pinkeye, elevated temperature, dyspnea, and bloat were observed in some animals during the trial. These health problems were not believed to be related to the experimental treatments.

B.3 Trial ASR 15095

- 1) Type of Study: Dose confirmation study in cattle with induced infections of lungworms.
- 2) Investigator: Bruce N. Kunkle, D.V.M., M.S., Ph.D. Merial Limited

Fulton, Missouri

3) General Design:

- a. Purpose: To determine the period after treatment during which infections of lungworms are controlled.
- b. Animals: Twenty (20) Holstein castrated male calves (10 per group), approximately 5 to 10 months old and weighing 195 to 304 kg at the start of the study were used. Animals were free of patent infections at the time of treatment.
- c. Treatment Groups: There were 2 treatment groups. One group received IVOMEC Pour-On and the other group was a negative control that received the vehicle for IVOMEC Pour-On topically at 1 mL/10 kg body weight.
- d. Infection: Infective larvae were given to each animal daily, starting on the day of treatment, according to the following schedule: *Dictyocaulus viviparus* (100 per day for 28 days).
- e. Dosage Form: The dosage form was IVOMEC Pour-On topical solution, 5 mg ivermectin/mL.
- f. Route of Administration: Topical.
- g. Dose: 1 mL/10 kg body weight (500 mcg ivermectin/kg body weight) once.
- h. Test Duration: 9 days after treatment.

- i. Pertinent Variables Measured: Worm counts were determined at necropsy, 49 days after treatment, 21 days after the last *Dictyocaulus viviparus* larvae were administered.
- 4) Results: There was an adequate level of infection in 9 of the control animals. Efficacy is summarized in Table 2.3:

Table 2.3 Trial ASR 15095 - Percent Efficacy IVOMEC Pour-On Against

Dictyocaulus viviparus

Persistent Effect Period	Geometric Mean in Controls	Geometric Mean in Treated	% Efficacy of IVOMEC Pour-On
28 days	15.7	0	100

5) Adverse Reactions: Inappetence, loose stool, depression, and a watering right eye were observed in some animals during the trial. These health problems were bit believed to be related to the experimental treatments.

B.4 Trial ASR 15110

- 1) Type of Study: Dose confirmation study in cattle with induced infections of gastrointestinal roundworms.
- 2) Investigator: Edward G. Johnson, D.V.M.

Johnson Research Parma, Idaho

- 3) General Design:
 - a. Purpose: To determine the period after treatment during which infections of gastrointestinal roundworms are controlled.
 - b. Animals: Thirty (30) Holstein male calves (10 per group), approximately 4 to 12 months old and weighing 130 to 186 kg at the start of the study were used. Animals were clear of patent infections at the time of treatment.
 - c. Treatment Groups: There were 3 treatment groups. One group received IVOMEC Pour-On. The negative controls received no treatment. One group received a medication which is not pertinent to this approval and is not reported.
 - d. Infection: Infective larvae were given to each animal daily, starting on the day of treatment, according to the following schedule: Cooperia oncophora & punctata (1000 per day for 21 days), Trichostrongylus axei (500 per day for 21 days), and Oesophagostomum radiatum (100 per day for 28 days). There were larvae of

other genus species given for various lengths of time that are not pertinent to this approval and are not reported.

- e. Dosage Form: The dosage form was IVOMEC Pour-On topical solution, 5 mg ivermectin/mL.
- g. Route of Administration: Topical.
- g. Dose: 1 mL/10 kg body weight (500 mcg ivermectin/kg body weight) once.
- h. Test Duration: 49 days after treatment.
- i. Pertinent Variables Measured: Worm counts were determined at necropsy, 49 days after treatment, 28 days after the last *Cooperia* spp. and *T. axei* larvae and 21 days after the last *O. radiatum* larvae were administered.
- 4) Results: There was an adequate level of infection in at least 6 control animals for *C. punctata, C. surnabada, T. axei,* and *O. radiatum.* Efficacy is summarized in Table 2.4:

Table 2.4 Trial ASR 15110 - Percent Efficacy IVOMEC Pour-On 21-day or 28-day

persistent effect periods

Nematode	Persistent	Geometric	Geometric	% Efficacy of
Species	Effect	Mean in	Mean in	IVOMEC Pour-
	Period	Controls	Treated	On
C. punctata	21	1470.7	27.0	98.2
C. surnabada	21	258.7	15.0	94.2
T. axei	21	588.7	29.1	95.1
O. radiatum	28	278.8	18.0	93.4

5) Adverse Reactions: One animal was found to have subacute pneumonia at necropsy. This health problem was not believed to be related to the experimental treatments.

B.5 Trial ASR 15111

- 1) Type of Study: Dose confirmation study in cattle with induced infections of gastrointestinal roundworms.
- 2) Investigator:

Bruce N. Kunkle, D.V.M., M.S., Ph.D.

Merial Limited Fulton, Missouri

- 3) General Design:
 - a. Purpose: To determine the period after treatment during which infections of gastrointestinal roundworms are controlled.

- b. Animals: Thirty (30) Holstein heifer calves (10 per group), approximately 5 to 6 months old and weighing 165 to 268 kg at the start of the study were used. Animals were free of patent infections at the time of infection.
- c. Treatment Groups: There were 3 treatment groups. One group received IVOMEC Pour-On. The negative controls received no treatment. One group received a medication which was not pertinent to this approval and is not reported.
- d. Infection: Infective larvae were given to each animal daily, starting on the day of treatment, according to the following schedule: Cooperia punctata (1000 per day for 21 days), Trichostrongylus axei (500 per day for 21 days), and Oesophagostomum radiatum (100 per day for 28 days). There were larvae of other genus species given for various lengths of time that were not pertinent to this approval and are not reported.
- e. Dosage Form: The dosage form was IVOMEC Pour-On topical solution, 5 mg ivermectin/mL.
- h. Route of Administration: Topical.
- g. Dose: 1 mL/10 kg body weight (500 mcg ivermectin/kg body weight) once.
- h. Test Duration: 49 or 50 days after treatment.
- i. Pertinent Variables Measured: Worm counts were determined at necropsy, 49 or 50 days after treatment, 28 or 29 days after the last *Cooperia* spp. and *T. axei* larvae and 21 days after the last *O. radiatum* larvae were administered.
- 4) Results: There was an adequate level of infection in at least 6 control animals for C. punctata, T. axei, and O. radiatum. Efficacy is summarized in Table 2.5:

Table 2.5 Trial ASR 15111 - Percent Efficacy IVOMEC Pour-On 21-day or 28-day

persistent effect periods

Nematode Species	Persistent Effect Period	Geometric Mean in Controls	Geometric Mean in Treated	% Efficacy of IVOMEC Pour-On
C. punctata	21	2917.8	1.8	99.9
T. axei	21	2122.8	1.5	99.9
O. radiatum	28	174.2	1.7	99.0

5) Adverse Reactions: Soft stool, bloody stool, abdominal swelling, nasal discharge, depressed appetite, and elevated temperature were observed in three nonmedicated control animals during the trial. These health problems were not believed to be related to the experimental treatments.

C. Substantial Evidence for Persistent Effectiveness Against Damalinia bovis

Two pivotal studies were conducted in the United States to evaluate the persistent activity of IVOMEC Pour-On in preventing infestation of treated cattle with Damalinia bovis. The studies had similar designs with separate groups of lice-free cattle being exposed to infested cattle for either 42 to 49 days after treatment or 49 to 56 days after treatment with ivermectin administered in its final formulation at a dose level of 0.5 mg/kg body weight. The efficacy was determined by comparing the geometric mean lice counts of the treated groups with those of an untreated control group on two separate count days post introduction of infested cattle. An adequate level of infestation had to be present in at least six infested control animals in order for the study to be acceptable. Lice counts were transformed to the natural logarithm (count + 1) for calculation of the geometric means. Treated and control groups were compared at each post-treatment time point using Wilcoxon's rank sum test. The period of persistent activity was defined as the time during which the efficacy against lice was demonstrated to be $\geq 90\%$.

For an indication to be granted, a minimum of two studies showing 90% efficacy was required at each persistent effect period. The new indication of persistent effect against *Damalinia bovis* for 56 days after treatment is supported by Trial Number PR&D 0045401 and Trial Number PR&D 0045402. The two trials are individually summarized below.

C.1 Trial Number PR&D 0045401

- 1) Type of Study: Dose confirmation study in cattle with natural infestations of lice.
- 2) Investigator:

K.E. Sterner, B.S., D.V.M.

Sterner Veterinary Clinic

Ionia, Missouri

- 3) General Design:
 - a. Purpose: To evaluate the persistence of effect of topically administered ivermectin at 500 mcg/kg body weight to prevent the establishment of lice (*Damalinia bovis*) by natural transfer.
 - b. Animals: Thirty (30) louse-free female Holstein calves, approximately 6 months old and weighing 119 to 244 kg on Day -1 were used as principle animals. Thirty (30) female and male castrate Holstein or Holstein crossbred calves, weighing 124 to 243 kg on Day 48 were used as donor animals. To ensure the principle animals were free of lice, they were treated topically with Vapona spray on Days -19 and -5 according to the manufacturer's recommendations and were free of lice as confirmed by a pretreatment examination on Day 0.

- c. Treatment Groups: There were 3 treatment groups. Two groups received IVOMEC Pour-On, one on Day 0 and the other on Day 7. The negative control group received a placebo vehicle that resembled the appearance of the test drug.
- d. Infestation: Each principal animal was naturally infested by exposure to donor cattle shown to have infestations of *Damalinia bovis*. Beginning on Day 49, each principal animal was exposed to one donor animal for 7 days. Following exposure, donor animals were removed on Day 56.
- e. Dosage Form: The dosage form was IVOMEC Pour-On topical solution, 5 mg ivermectin/mL.
- i. Route of Administration: Topical.
- g. Dose: 1 mL/10 kg body weight (500 mcg ivermectin/kg body weight) once.
- h. Test Duration: 84 days after treatment.
- i. Pertinent Variables Measured: Lice counts were conducted on principal animals on Days 70 and 84 to ensure sufficient time for any lice successfully transferred to become established. These counts at each time point were calculated for each animal by summing the counts from 12 predilection sites.
- 4) Results: There was an adequate level of infestation in at least 6 control animals for *Damalinia bovis*. Efficacy is summarized in Table 2.6:

Table 2.6 Trial Number PR&D 0045401 - Percent Efficacy IVOMEC Pour-On Against Damalinia bovis

		Geometric	Geometric	% Efficacy	P-value ²
Challenge	Count	Mean in	Mean in	of IVOMEC	
Period ¹	Day	Controls	Treated	Pour-On	
42 to 49 days	70	23.0	0.0	100	< 0.0001
42 to 49 days	84	44.4	0.0	100	< 0.0001
			:		
49 to 56 days	70	23.0	0.0	100	< 0.0001
49 to 56 days	84	44.4	0.0	100	< 0.0001

¹Days after treatment that principal animals were exposed to donor animals. Cattle treated on Day 0 were challenged 49 to 56 days after treatment and cattle treated on Day 7 were challenged on 42 to 49 days after treatment.

²The p-value represents the exact probability of a statistical difference between the treatment group and the control group using the Wilcoxin rank sum test in SAS.

5) Adverse Reactions: No treatment related health problems were observed.

C.2 Trial Number PR&D 0045402

1) Type of Study: Dose confirmation study in cattle with natural infestations of lice.

2) Investigator: J.E. Holste, D.V.M.

Merial Limited Fulton, Missouri

3) General Design:

- a. Purpose: To evaluate the persistence of effect of topically administered ivermectin at 500 mcg/kg body weight to prevent the establishment of lice (*Damalinia bovis*) by natural transfer.
- b. Animals: Thirty (30) louse-free female Holstein calves, approximately 6 months old and weighing 173 to 224 kg on Day -1 were used as principle animals. Thirty (30) female and male intact and castrate Holstein or Holstein crossbred calves, weighing 91 to 257 kg on Day 48 were used as donor animals. To ensure the principal animals were free of lice, they were treated topically with Vapona spray on Days -19 and -5 according to the manufacturer's recommendations and were free of lice as confirmed by a pretreatment examination on Day 0.
- c. Treatment Groups: There were 3 treatment groups. Two groups received IVOMEC Pour-On, one on Day 0 and the other on Day 7. The negative control group received a placebo vehicle that resembled the appearance of the test drug on Day 7.
- d. Infestation: Each principal animal was naturally infested by exposure to donor cattle shown to have infestations of *Damalinia bovis*. Beginning on Day 49, each principal animal was exposed to one donor animal for 7 days. Following exposure, donor animals were removed on Day 56. Counts were conducted on principal animals on Days 70 and 84 to ensure sufficient time for any lice successfully transferred to become established.
- e. Dosage Form: The dosage form was IVOMEC Pour-On topical solution, 5 mg ivermectin/mL.
- j. Route of Administration: Topical.
- g. Dose: 1 mL/10 kg body weight (500 mcg ivermectin/kg body weight) once.
- h. Test Duration: 84 days after treatment.
- i. Pertinent Variables Measured: Lice counts conducted on principal animals on Days 70 and 84 were calculated for each animal by summing the counts from 12 predilection sites.

4) Results: There was an adequate level of infestation of *Damalinia bovis* in at least 6 control animals on both count days. Efficacy is summarized in Table 2.7:

Table 2.7 Trial Number PR&D 0045402 - Percent Efficacy IVOMEC Pour-On

Against Damalinia bovis

		Geometric	Geometric	% Efficacy	P-value ²
Challenge	Count	Mean in	Mean in	of IVOMEC	
Period ¹	Day	Controls	Treated	Pour-On	
42 to 49 days	70	133.7	0.0	100	< 0.0001
42 to 49 days	84	139.1	0.0	100	< 0.0001
				ę	
49 to 56 days	70	133.7	0.0	100	< 0.0001
49 to 56 days	84	139.1	0.0	100	< 0.0001

Days after treatment that principal animals were exposed to donor animals. Cattle treated on Day 0 were challenged 49 to 56 days after treatment and cattle treated on Day 7 were challenged on 42 to 49 days after treatment.

5) Adverse Reactions: No treatment related health problems were observed.

3. TARGET ANIMAL SAFETY

No further target animal safety data were required from the original approval as discussed in the parent NADA 140-841 FOI Summary dated December 4, 1990.

4. HUMAN SAFETY

No further human food safety data were required from the original approval as discussed in the parent NADA 140-841 FOI summary dated December 4, 1990 and in the supplement to NADA 128-409 FOI summary (IVOMEC Injection for Cattle) dated September 12, 1994. There is a 48-day withdrawal period for slaughter, a withdrawal period for milk has not been established, and a withdrawal period has not been established for pre-ruminating calves.

5. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that IVOMEC (ivermectin) Pour-On for Cattle when administered once at 500 mcg/kg body weight is safe and effective for the addition of the following new persistent effect indications: Dictyocaulus viviparus for 28 days, Cooperia surnabada for 14 days, and Damalinia bovis for 56 days. Also, the persistent effect periods are extended for the following: Oesophagostomum radiatum from 14 to 28 days and Cooperia punctata and Trichostrongylus axei from 14 days to 21 days.

²The p-value represents the exact probability of a statistical difference between the treatment group and the control group using the Wilcoxin rank sum test in SAS.

The following has been added to the residue information section of the labeling, "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal."

The Agency has concluded that this product retain over-the-counter marketing status because adequate directions for use have been written for the layperson and the conditions of use prescribed on the label are likely to be followed in practice.

In accordance with 21 CFR 514.106(b)(2)(v), this is a Category II change which did not require a reevaluation of the safety or effectiveness data in the parent application.

Under Section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for THREE years of marketing exclusivity beginning on the date of approval. The three years of marketing exclusivity applies only to the new persistent effect indications and the extension of 3 already approved persistent effect indications listed above.

No patent information was submitted with this application.

6. ATTACHMENTS

Facsimile Labeling is attached as indicated below:

- A. 250 mL Leaflet front (Page 1 and 2), label front, carton
- B. 1 L Leaflet, front and base, carton
- C. 2.5 and 5 L Label front and back, carton
- D. 20 L label front and back, outsert front and back (page 1 and 2)
- E. Package insert for all container sizes

Persistent Activity
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Parasiticide

Contains 5 mg ivermectin/mL

ponk-on ter cattle (ivermectin) WOWEG.



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hermeolin has been associated with adverse needlone in sensitive dogs; theretone, IVOMEC Pour-On is not recommended for use in Antiparsatic activity of ivermectin will be impaired if the formulation is applied to areas of the sidn with mange scales or leadons, or with demailoses or adherent materials, e.g., calsed must or manue.

Cloudness in the formulation may occur when IVOMEC Pour On is stored at temperatures below 32°F. Allowing to warm at room temperatures wit restore the normal appearance without affecting

egycsch.

This product is for application to aidn surface only. Do not give orally or

Do not use when rain is expected to wel cattle within six hours elittes should not be treated when help or hide is wel since reduced elitte should not be treated when help or hide is well since reduced.

Close container lightly when not in use, Use only in well-ventilated areas or outdoors.

Store away from excessive heat (104°F/40°C) and protect from light.

breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for year. RESIDUE MUCORMATION: Caule must not be treated within 48 days of staughter for human consumption. Because a withdrawait time in milk has not been a set of the fine set of the catile of sets.

Veen's besuit about of the set betabled in the volume at most of the control of the volume at most of the set of the volume and the volume and the volume and the volume as the volume and week a volume of the volume and week at the volume and week and week. It socidentially with value and veek and week at the volume and veek and veek at the volume and veek and veek

WARNING! FLAMKABLE! KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME. AND OTHER, SOURCES OF, IGNITION.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information: To report adverse effects, obtain an MSDS or for assistance, contact Merial at 1-988-631-4251.

Keep this and all drugs out of the reach of children. NOT FOR USE IN HUMANS. WARNING

reading performance. on bert richtw natiteitemet formulation which had no effect on Studies conducted in the U.S.A. Inque demonstrated the salety organ for homedin. Based on pleams levels, the studies of special princeton is expected to be sale less than it indented in the property of the salety of the salety of the salety property.

When the interval between uses of the applicator gun is expected to screed it? bounc, decorated the gun, exwell though and set than the gun and seem from the product container, and the product from the gun and though beck into the product container and replaces the shipping cap, and the product container and select the shipping cap.

heart the open and of the draw-of flubing by an appropriate chaint, applicable, Allean draw-off kibing to the cap with the stem. Replace the subspirit cap with the cap having the draw-off subing. Gently prime the subspirit cap with the cap having the cap and a subspirit cap and the property of the cap and the

Use deating equipment (applicator, draw-off babing, cap with stam) to deating equipment (application, draw-off babing, cap deating and officer deating compatible with 10 Violet Officer (compatible with 10 Violet Officer (application) and officer deating and officer deating the does not proper use and manifesters of the deating the does not proper use and manifesters of the deating the does not proper use and manifesters of the deating to death of the deating of the d CYS II OSISO L Pacity

the Protector Dranch Gun, the gun and tubing must not be washed. of beloogs at mg tolastige will to seat neemfed levent and nerfly and mort gridd file-wash but any will bearcock , aroun's St beacar iced gridds har mg will netted only diffyrme bits seriative budden most amended laborate to broomen herway of 1 anniatives budden and an herboard and present prices to any any and soft budden and pre-Follow the manufacturers directions for adjusting the dose.

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CONTINUE D HIN IVERHIECHINHE

Parasiticida

Consult your veterinarian for assistance in the diagnosis, stment and control of parasitism.

INTRODUCTION

"NONEC (ivenmedin) Pour-On delivers internal and external perasite control in one convenient low-volume application. Discovered and developed by actentists from Merck Research Laboratories, IVOMEC Pour-On contains Ivenmedin, a unique chemical shifty.

MODE OF ACTION

incube the ACTION invarmed in is a member of the macrocylic factone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated coloride ion channels which occur in invertebrate nerve and muscle

This leads to an increase in the permeability of the cell membrane to chloride lone with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the paraette. Compounds of this class may also hereat with other ligand-guided chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA)

The margin of safety for compounds of this class is attributable to the tax; that mammals do not have glutarnate gated chloride channels, the macrocyclic factones have a low affinity for other mammalian agand-gated chloride channels and they do not readily cross the

INDICATIONS

IVOMEC Pour-On applied at the recommended dose level of 500 mog/kg is indicated for the effective treatment and control of these parasites.

Ostertagia ostertagi (including inhibited stage)		(adults and L_4)
Haemonchus placel		(adults and L ₄)
Trichostrongylus axel		(adults and L.)
T. colubritornils		(adults and L ₄)
Cooperia oncophora	ì	(adults and L.)
Cooperia punctata		(adults and L ₄)
Cooperia surnabada		(adults and L ₄)
Strongyloides papillosus		(adults)
Oesophagostomum radiatum		(adults and L ₄)
Trichuris spp.	,	(adults)
Lungworms		
Diotyocaulus viviparus		(adults and L ₄)
Cattle Grubs		(parasitic stages
**		

H. Roeatum

Linognathus vituli Haematopinus eurystemus Damatinia bovis Solenopotes capillatus

Hom Files Haematobia intians

IVOMEC Pour On has been proved to effectively control infections and to protect cattle from re-infection with: Oesophagostomum radiatum and Dictyocaulus viviparus for 28 days after treatment; Cooperia punctata and Trichostrongylus axel for 21 days after treatment; Ostertagia octertagi, Haemonchus placel, Cooperia ondophora and Cooperia surrabada for 14 days after treatment; Damalnie bovis for 58 days after treatment.

Treatment of Cattle for Horn Files (Heemelobia Initians) for up to 28 days after doeing. For best results INCEC Pour-On should be part of a parasite control program for both internal and external perasites of the specific program for both internal and external perasites on the spidemiology of these perasites. Consult your veteringsten or an entomologist for the most effective timing of

DOSAGE

The dose rate is 1 mL for each 22 to of body weight. The formulat should be applied along the topline in a narrow strip extending from the withers to the tellhead.

ADMINISTRATION

Squeeze-Measure-Pour System 6.5 fl oz/250 mL Bottle with 25 mL Metering Cup)

Attach the metering cup to the bottle. Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knumed cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. The off (STOP) position will close the system between dosing.

Squeeze-Messure-Pour System (33.8 fl oz/1 Liter Bottle with 50 mL Metering Cup)

Attach the metering cup to the bottle.

Set'the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. When 220 ib (10 mL) or 330 ib (15 mL) dose is required, turn the pointer to "STOP" before delivering the dose. The off (STOP) position will close the system between dosing.

doeing applicator, checking for leeks

When the interval between uses of the applicator oun is expected to exceed 12 hours, disconnect the gun, draw-off tubing and cap with stem from the product container, empty the product from the gun and tubing back into the product container and replace the shipping cap.

ANIMAL SAFFTY

Studies conducted in the U.S.A. have demonstrated the safety margin for hermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

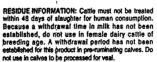
WARNING NOT FOR USE IN HUMANS. Keep this and all drugs out of the reach of children.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Menal at 1-888-637-4251.

WARNINGI FLAMMABLEI KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION.

This product should not be applied to self or others because it may Into product should not be appear to select critical success in the skin.

To minimize accidental skin contact, the user should wear as long-sleeved shirt and rubber gloves. If accidental skin contact cours, wash immediately with soep and water. If accidental eye exposure occurs, flush eyes immediately with water and seek



Store away from excessive heat (104°F/40°C) and protect from light.

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when heir or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours

This product is for application to skin surface only. Do not give grally or

Cloudiness in the formulation may occur when IVOMEC Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting

Antiparastic activity of Ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dematoses or achievent materials, e.g., caked mud or manure.

ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in energies other than cattle

When to Treat Cattle with Grubs IVOMEC Pour-On effectively controls all stages of cattle grubs. However, proper fining of treatment is important. For the most effective results, cattle should be treated as soon as possible after the end of the results, cause ancount presents are such as present as each are not not an elective must be high season. While this is not peculiar to hermeckin, destruction of Hypoderma larvae (cattle grubs) at the period when these grubs are in vital areas may cause undestrable host-parasite reactions. Killing Hypoderma lineatum when it is in the exophageal tissues may cause block killing H, book when it is in the vertebral canal. may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development.

Cattle treated with IVOMEC Pour-On at the end of the fly season may be re-treated with IVOMEC during the winter without danger of grub-related reactions. For jurther information and advice on a planned parasite control program, consult your veterinarian.

Environmental Safety

Studies indicate that when Ivermectin comes in contact with soil it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish and certain aquatic least six hours after treatment. Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to tabel directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

IVOMEC Pour-On is available in an 8.5 fl oz/250 mL bottle or 33.8 fl oz/1 L bottle with a squeeze-measure-pour system, or in an 84.5 ft oz/2.5 L or 169 oz/5 L collapsible pack, or 676 ft oz/20 L container intended for use with appropriate automatic dosing equipment.

IVOMEC and Cattle Head Logo are registered trademarks of Merial Limited.

Merial Limited, a company limited by shares registered in England and

may ceuse staggering or paralysis. Cattle should be treated either before or after these stages of grub development. destruction of Hypodemse laivee (cattle grabs) at the period when these grades are in this bases may cause undestable as the resolutes. Talking hypodemse frees may enter it is in the westernal exercise may cause blood may find it hower may entering cancel assures may cause blood from Infind. It hower may entering cancel WOMEC Pour-On effectively controls all stages of cettile grube. Powware, proper timing of westernar is encounted. The most effective results, cardie should be freeded as soon as possible after the end of the results, cardie should be freeded as soon as possible after the whomen's peet fly, which if y sessor, While this is not peeular to homenotin.

Cattle treated with IVOMEC Pour-On at the end of the ity season may

Environmental Selety, Studies indicate that when ivermedin comes in contact with soil it be re-treated with IVOMEC during the winter without danger of gub-releted reactions. For further information and achics on a planned parasise control program, consult your velentrarian.

Estit most not ettied to insenteer! Cooperle punctate and Trichostrongyha axel for 21 days after freatment. Cotesties, existing, teachment. Cotesties, teachment of Cooperla surrelated for 14 days after treatment. Demainstrate boxes for 56 days after treatment.

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(LE if oz/250 mL Bottle with 25 mL Metering Cup)

Aftach the metering cup to the bottle.

Set the dose by tuming the top section of the rup to stilgn the correct body weight with the potales on the tumind cap. When hold the body weight with the potales to the form the tumind cap. When hold the body weight will expense of the major and the section to the contract of the cont

required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. The Off (GIDP) position will cook into system between dosing.

Squeeze-Measure-Pour System (33.8 ff ozi i Liter Bottle with 50 mL Metering Cup)

Attach the metering cup to the bottle.

Hold the bottle upright and aqueeze it to deliver a slight excess of the required dose as indicated by the calbraton lines. Set the dose by turning the top section of the cup to stign the correct body weight with the pointer on the turnied cap. When the correct body weight is between markings, use the include cap. When

By 'cleateful file pressive, In so does white plants with galler of the control series in the control series control series in the control series control serie

System Derween dosing.

Coursect are abbijostos diru to are cogebagos back se togowa: (84.5 if oz/2.5 L Pack and 169 if oz/5 L Pack)

Altech its open and of the draw-of tubing to the dosting equipment. (Because of the solvents used in the solvents used in the formulation, only the Porech Curr flow thou hat tument Supplies Limited, or activisient, its monitor on office and other problems are also that one of the solvents of the solvents of the solvents of seasons or seasons or seasons.

resulting in locking, incorrect doesge or leakege.)
Replace the shipping cap with the draw-off cap and lighten down.
Attach draw-off subing to the draw-off cap.

Gordy prime the applicator gun, checking for leaks.

Front

MERIAL GLOBAL PACKAGING TECHNOLOGY

Васк

Morial United, a company limited by strates registered in England and Wibbs (wightered unmbs 2582515) will be registered with the substant Avenue, Randomphan Avenue, Hardow Business Park, Harlow Wibssell 1919 516, England, and domesticated in the substant Park 1919 516, England, and domesticated in the substant Park 1919 516.

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bortle with a squeeze-measure-pour system, or in an 84,5 if ox/2,5 L or 169 ox/5 L collapsite pack, or 676 if ox/20 L container intended for use

I I/ONEC Pour-On its available in an 8.5 it ox/250 mil. bottle or 33.8 it oz/1 L.

reproduction. The integnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of

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needly and tightly binds to the soll and becomes inactive over time. Free Ivermectin may adversely affect fish and certain aquatic organisms. Do not permit cate to enter telesa, streams or ponds for at

with appropriate automatic dosing equipment.

A.2.U ,0161-00000

Mental Limited 3239 Satellite Blvd. Duluft, Georgia

USB PANTONE MATCHING SYSTEM

BISCK tor an accurate color representation.

PMS 185 Red

Telephone #: (678) 638-3302 Graphic Designer: Patricia Greene

1050-1445-0F

Rev. 08-2003

695,981 4,199,569 Delaware, USA as Merial LLC.

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A - 03/10/03 Date: 18 August 2003

Revision - Date:

0 - 08/12/03 C - 03/58/03 (2W) Noie this revision

CPT purposes ONLY history is for internal

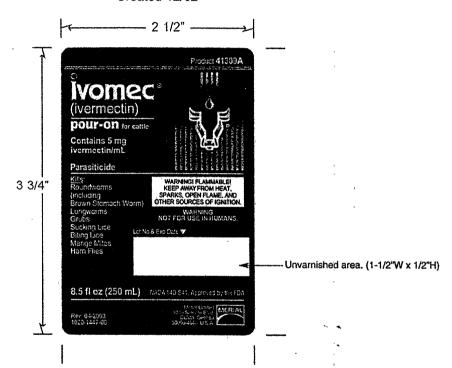
Project: Revise Persistency Activity Brand: Nomec Pour-On Country: ASU Originator: Bruce Somerville Client: Ruminant Animal Global Enterprise

Component Description:

A.2.U , 30006. A.3 , rhulud 3239 Satellite Bivd.

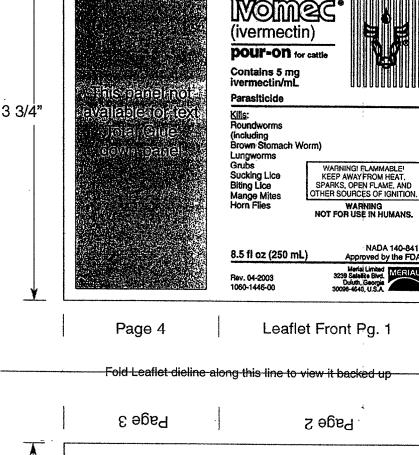
> Component # 1050-1445-0F

Dieline for Merial 250mL Front Label Final Label size 3 3/4" x 2 1/2" Created 12/02



Note: Cyan callouts do NOT Print

MERIAL GLOBAL PACK	AGING TECHNOLOGY	Component # 1020-1447-00
Client: Ruminent Animal Global Enterprise Originator: Tanyja Porcha Country: USA Brand: Ivomec Pour-On Project: 250mL Component Description: Label (front)	Graphic Designer: Chandra Bulmer Telephone #: 678-638-3261 Date: 13 June 2003 Revision - Date: A - 03/07/03 Role: this revision B - 03/26/03 history is for Internal C - 04/15/03 PRO GPT purposes ONLY D - 06/13/03 Revised PRD	Colors: Use PANTONE MATCHING SYSTEM for an accurate color representation. PMS 874 Gold Special Brown (c=0/m=74/y=100/k=80) PMS 185 Red Magenta Yellow Magenta Dutum, 64 30096, US. A MIGRIAL DUTUM, 64 30096, US. A MIGRIAL DUTUM, 64 30096, US. A



Total Leaflet Length is 3 7/8

Product 41309A

Syan does NOT

Project: 250m

Originator: Country: Brand:

3 3/4"

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced. Close container tightly when not in use. Use only in well-verifiated areas or outdoors. Store away from excessive heat (104°FM0°C) and protect from light. PRECAUTIONS

Do not contaminate water by direct applications or by improper disposal of drug containers, or by improper disposal of drug containers in an approved landtitle or by incineration.

Nemecin. has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in species other than calife.

Antiparasilic activity of ivermectin will be impaired it the formulation is applied to resone, or of the such middle and and or manue, with demandress or edecard materials, e.g., esked mud or manue.

Cloudiness in the formulation may occur when VVOMEOB (with pru-un) is stored at amountaines below 62°F. Allowing to warm at noon femperature will restone the normal noon femperature will restone the normal suppearance without a felecting efficiency.

This product is tot application to stan surface only. Do not give orally or parenterally.

Do not use when rain is expected to wel callle within six hours after treatment.

RESIDUE INFORMATION: Catilo must not be brosled within 46 days of staughter for human consumption, Because a withdrawal inne in mik has not been established the not use a manuale day catilog for the people of the catilogram of the people of

A.C.U is about the trade of Meriel Limited. Togistered trademarks of Meriel Limited. U.S. Pat. 4,199,569

This product should not be applied to sell or others because it may be initiating to burnen others because it may be initiating to burnen side and eyes and expendental side contract, if the user should wear a locoferdia side contract occurs, was interesting side contract occurs, with making the side of side o

WARNING: FLAMMABLE: KEEP AWAY FROM HEAT, SPARKS, OPEU FLAME, AND OTHER SOURCES OF IGUITION,

office Mishels Salety Data Sheet (MSDS) sheet sheets stated compared sealety contains more destated occupational salety inhomation. To report adverse effects, obtain an MSDS or for sessionse, contact the season of the season o

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Recommended Dose: 1 mL per 22 to of body See package insent for complete in and use directions. INDICATIONS

For the tealment and control of gastroinrestinal roundworms (including funds.) homsee, sucking and brinds fice, and sarcoptic
mange miles in cattle.

See parkent in cattle.

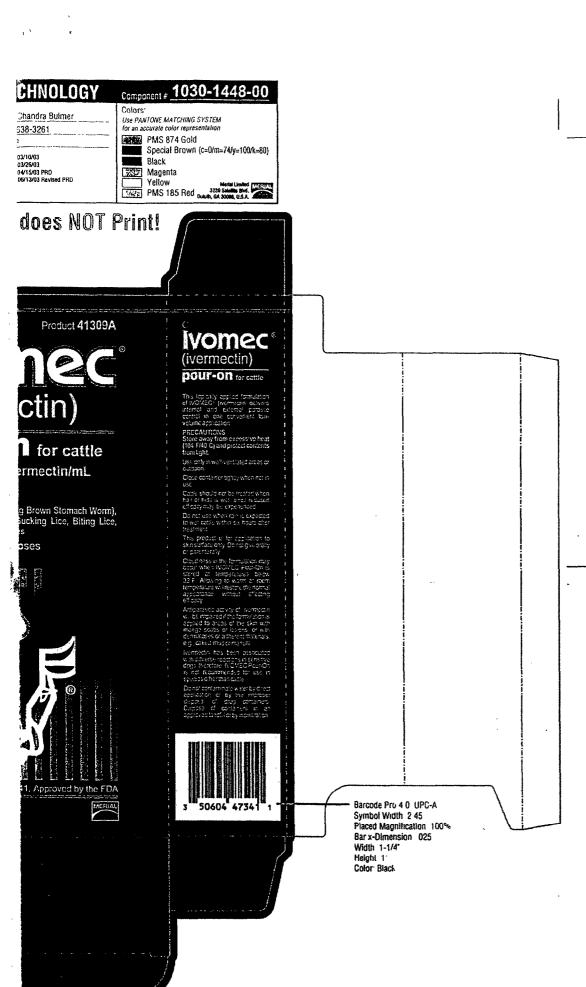
Consult your veterinarian for assistance in the diagnosts, treatment and control of parasitism.



W.

NADA 140-841, Approved by the FDA

Mertal Limited 3239 Satelike Blvd. Dufuth, Georgia 30096-4640, U.S.A



Product 413 (Jm 025) zc II 2.8 Contains 5 mg ivermectinimL DOUR-OR for cattle (ivermectin) NOWSC.

Component # 1030-1448-00 MERIAL GLOBAL PACKAGING TECHNOLOGY Colors Client Ruminant Animal Global Enterprise Graphic Designer Chandra Bulmer Use PANTONE MATCHING SYSTEM Originator, Tanyja Porcha Telephone # 678-638-3261 for an accurate color representa PMS 874 Gold Country: USA Date 13 June 2003 Special Brown (c=0/m=74/y=100/k=80) Brand. <u>Ivomec Pour-On</u> Revision - Date A - 03/10/03
Note this revision B 03/26/03
C - 04/15/03 PRD D - 06/13/03 Revised PRD D - 06/13/03 Revised PRD Black Project: 250mL Magenta Yellow PMS 185 Red Outsta, GA 2000s, U.S.A. Component Description: Tuck Carton

Cya: does NOT Print!

Product 41309A

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on for cattle

or assistance in the diagnosis, treatment and

of gastrointestinal roundwarms, jincluding fungsionns grups nom files, sucking and invites in dating

22 to of body weight. The formulation should comow strip extending from the witners to the

op section of the cup to arigh the contect body a knowled cap. When body weight is between

dose automatically adjusts to the correct level case. The on (STOP) position will diose that

Lot No & Exp Date ▼

Ivomec® (ivermectin)

pour-on for cattle

Animal Safety

Warningi Flammablei Keep away from heat. Sparks, open flame. And other sources Of Ignition.

RESIDUE INFORMATION:

Rev. 04-2093 1030-1448-00 ivermectin)

pour-on for cattle

Contains 5 mg ivermectin/ml.

Parasiticide 8

Kills: Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies

Contains 10-550 lb Doses



NADA 140-841. Approved by the FDA

8.5 fl oz (250 mL)

ivomec* (ivermectin)

DOUT-On for cettle



50604 4734

Lagel Maker Pro Code 128, C-128/1 Width 1 181 rieight 1/2 Joior Black

Sym Place Bar x No Vain St. Area 1.25 x : 25

Product 41309A

(Jm 03S) xo 11 2.8

Contains 5 mg ivermeetinim

pont-on to-mod (ivermectin)

NOWSC

MERIAL GLOBAL PACKAGINE

Client Rum nan An ma G oba Enterpr se Origina or Tanyja Porc a

Country USA

Brand vomec Pour-On

Projec 250mL

Componen Descrip on Tuck Carton

Graph c Des Te ephone * Date 13 Ju

Rev s on - D How this evision history a lor mission PT purposas (IML)

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Wellfelm v incom-Contains ---

vomec (ivermectin)

pour-on for cattle

Consult your vaterinarian for assistance in the diagnosis, treatment and control of parasitism.

INDICATIONS

For the treatment and control of gostromestinal trunductins (including introductions) for disease, including introductions of control bring to and sarcepter mange nates in earlier. See package insert for complete indications and use directions.

DODAGE
The date rate is 1 mil for each 22 to of body weight. The formulation should be applied along the top-inte in a namow strip extending from the witners to the taffecal.

ADMINISTRATION
Altison the motioning cup to the bottle.
Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knutled cap. When body weight is between nathings use the higher setting.
Had the bottle purpoid and societize if to celliver a significance of the required dose as indicated by the call protion lines.
By releasing the pressure, the dose culomatically adjusts to the correct level Title the bottle to celliver the cose. The off (STQP) position will dissert the system between dosing.



IVOMEC and Cattle Head Logo are registered trademarks of Merial Limited U.S. Pat 4,199,509

Lot No & Exp Date *

vome (ivermectin) pour-on for cattle

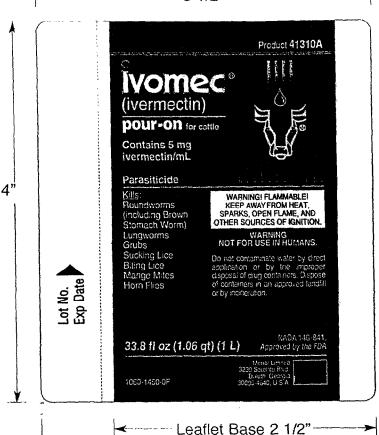
WARNING! FLAMMABLE KEEP AWAY FROM HEAT SPARKS, OPEN FLAME AND OTHER SOURCES OF IGNITION

RESIDUE INFORMATION: Colle must not be beiled volum 45 days of supporter

Rev. 04-2003 1030-1448-00

8.5 11 OZ (Z511 III.

Lacel Maker Pro Code 128 C-128/1 Width 1 181" Height 1/2" Color Black



well tolerated by breeding animals as is the subcutance formulation which had no effect on breeding performan-

WARNING NOT FOR USE IN HUMANS.

Keep this and all drugs out of the reach of children. The Material Safety Data Sheet (MSDS) contains I detailed occupational safety information. To report adveletes, obtain an MSDS or for assistance, contact Mer-1-888-637-4251.

WARNING! FLAMMABLE! KEEP AWAY FROM HEAT, SPARKS, OPEN FLAM AND OTHER SOURCES OF IGNITION

This product should not be applied to self or oth because it may be initiating to human skin and eyes absorbed through the skin. To minimize eccidental contact, the user should wear a long-sleeved shirt. rubber gloves. If accidental skin contact occurs, v= immediately with soap and water. If accidental exposure occurs, flush eyes immediately with water seek medical attention.

RESIDUE INFORMATION: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age, A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

4"

"t

Store away from excessive heat (104°F/40°C) a protect from light.

Use only in well-ventilated areas or outdoors. Close container tightly when not in use.

Page 6

MERIAL GLOBAL PACKAGING TECHNOLOGY

Client: Ruminent Animal Global Enterprise

Originator: Bruce Somerville

Country: USA

Brand: Ivomec Pour-On

Project: 1 Liter (Revise Persistent Activity)

Component Description: Outsert

Graphic Designer: Patricia Greene

Telephone #: 678-638-3302

Date: 18 August 2003

Revision - Date: A-03/28/03 Note. this revision history is for internat

B - 03/28/03 (SM) C - 08/18/03

GPT purposes ONLY

Facsimile Labeling

Component # 1060-1450-0F

Colors:

Use PANTONE-MATCHING SYSTEM for an accurate color representation.

PMS 874 Gold

Special Brown (c=0/m=74/y=100/k=80)

Black

Magenta

Yellow

Y BIOW
PMS 485 Red Duluth, GA 30096, U.S.A.

Page 5

ety margin for ivermedin. Based on plasma levels, the ically applied formulation is expected to be at least as office conducted in the U.S.A. have demonstrated the Y 134AC JAMI

Hector Drench Gun, the gun and tubing must not be and property of the separate of the supplication and new order to exceed its hours, deconnect the fund the world the product container and empty then duct into the product of the product low the manufacturer's directions for adjusting the dose. unty prime the applicator gun, checking for leaks.

place the shipping cap with the draw-off cap and lighten mr. Attach draw-off tubing to the draw-off cap. ach the open and of the draw-oil lubing to the desing upprent. (Because of the solvents used in them trulistion, only the Protector Drench Cun from nutristion. Supplies Limited, or equivalent, is trumented. Other applicators may exhibit compatibility compatibility of the supplies of th

wweet the applicator gun to the collapsible pack as TE U ONS T Lack and 169 U ONS T Pack) Mapsible Pack

tratesaring the pressure, the does automatically adjusts of the does. When the bother to deliver the does it mut along the does to required, the filt of TOP's before delivering the does. The off the does the system between dorsing.

cess of the reduked dose as indicated by the calibration

2 5/16"



NADA 140-841. Approved by the FDA

enal Limited

3ase 2 1/2"-

well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING NOT FOR USE IN HUMANS.

Keep this and all drugs out of the reach of children.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Merial at 1-888-637-4251.

WARNING! FLAMMABLE! KEEP AWAY FROM HEAT, SPARKS, OPEN FLAMF AND OTHER SOURCES OF IGNITION

This product should not be applied to self or others because it may be imitating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

RESIDUE INFORMATION: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not urie in trainit has not been established, do not use in fernale dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PRECAUTIONS

4"

Store away from excessive heat (104°F/40°C) and protect from light.

Use only in well-ventilated areas or outdoors. Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally

Cloudiness in the formulation may occur when IVOMEC® (ivermedin) Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

hermectin has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in species other than cattle.

recommenced for use in species orner than cattle.

When to Treat Cattle with Grubs

VOMEC Pour-On effectively controls all stages of cattle
grubs. However, proper timing of treatment is important. For
the most effective results, cattle should be treated as soon as
possible after the end of the heel fly (warble fly) season.

While this is not peculiar to inemedin, destruction of
Hypoderma larvae (cattle grubs) at the period when these
grubs are in vital areas may cause undesirable host-parasite
reactions. Killing Hypoderma lineaturn when it is in the groups are in vital a basis his procedure. When it is in the esophageal tissues may cause bloat; killing H. bovis when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of arub develooment.

Gattle treated with IVOMEC Pour-On at the end of the fly season may be re-treated with IVOMEC during the winter without danger of grub-related reactions. For turther information and advice on a planned parasite control program, consult your veterinarian.

Environmental Studies indicate soil it readily a inactive over tirr and certain agu lakes, streams c Do not contan improper dispos in an approved i As with other av of treated anim growth of pest source of food duration of suct When used aco expected to have dependent insec HOW SUPPLIE IVOMEC Pour-C 33.8 fl oz/1 L bol in an 84.5 fl oz/2 oz/20 L conta automatic dosine

Merial Limited 3239 Satellite Blvd Duluth, Georgia 30096-4640, U.S.I

Merial Limited, a o and Wales (registe PO Box 327, Sand Business Park, Ha domesticated in De

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Page 6

Page 7

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Rage 5

Раде 4

TECHNOLOGY

)esigner: Patricia Greene

e#: 678-638-3302

August 2003

- Date: A - 03/28/03

ion B - 03/28/03 (SM) vernal C - 08/18/03

ONLY

Studies conducted in the U.S.A. even demonstrated the saled on plasma levels, the sale on plasma levels, the sale of the sale ANEMAL SAFETY Dausen

Protector Drench Gun, the gun and tubing must not be When the interval between uses of the applicator gun is abpected to acceed 12 hours, disconned the gun and draw-38 tubing from the product sometime rand and the product from the gun and tubing back into the product from the gun and tubing back into the product from the gun and tubing back into the container. To pervent removal of special fubricants from the product from the container of the product from the container. Follow the manufacturer's directions for adjusting the dose. Gently prime the applicator gun, checking for leaks.

Replace the shipping cap with the draw-off cap. down. Attach draw-off tubing to the draw-off cap. Altach the open end of the draw-off hibing to the dosing delipment, (Because of the solvents used in the mort nous from the protector Dranch Gun to ministed, or equivalent, is instituted. The properties the protections may exhibit compatibility problems resulting in locding, incorrect dosage or leakage).

:SMOROE Counect the applicator gun to the collapsible pack as Collapsible Pack and 169 flozi5 L Pack)

(STOP) position will close the system between dosing. By releasing the pressure, the dose automatically adjusts of used to the dose. When the dose, we have the dose, then the dose is required to "\$\frac{37}{20}\text{ b} (15 mL) dose is required, the the dose. The off points to "\$\frac{37}{20}\text{ b} = \frac{37}{20}\text{ Seum

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration

Set the dose by furning the top section of the cup to align the contect body weight with the pointer on the funded cap. When body weight is behiven markings, use the higher

Attach the metering cup to the bottle. Squeeze-Messure-Pour System Squeeze-Messure-Pour System (33.8 if ozy Liner Bottle with 50 mL Metering Cup)

By releasing the pressure, the cose automatically adjusts to the correct level. Till the bottle to deliver the cose. The off (STOP) position will close the system between dosing. "SƏUİ

Hold the bottle upright and squeeze it to deliver a slight access of the regular dose as indicated by the calibration

Set the dose by turning the top section of the cup to stign the condition to weight with the pointer on the fourted cap. When body weight is between markings, use the higher

ADMINISTRATION
Squeeze-Measure-Pour System
Squeeze-Measure-Pour System
(45.5 fi oz/250 m.L Blottle with 25 m.L Metering Cup)
Attach the metering up to the bottle.
Attach the metering up to the bottle.

YOMEC Pour-On controls from files (Heamstobis imitans) for up to 28 days after define the controls of the control program for both financial and external passeties based on the epidemiology of these parasites. Consult your veterinarian or an entomologist for the most effective timing of applications. itment of Cattle for Horn Flies

Trichostrongytas axel for 21 days after treatment, Ostantagia ostantagi, Haemonchus placel, Coopenia oncophora and Coopenia sumabada for 14 days after treatment, Damaifnia bovs for 56 days after treatment.

a punctata and cautus viviparus e-infection with:

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adults) عبط الحلا) (ביל pue silube () bne slube () bne slube () bne slube (the sample (Pri pue sance

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TONE-MATCHING SYSTEM curate color representation.

PMS 874 Gold Special Brown (c=0/m=74/v=100/k=80)

Black

Magenta Yellow

"PMS 485 Red Dulluth, GA 30096, U.S.A."



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~8/8 Z ~

indicated for the

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudines in the formulation may occur when IVOMEC® (tvermectin) Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in species other than cattle.

recommended for use in species other than cattle.

When to Treat Cattle with Grubs

IVOMEC Pour-On effectively controls all stages of cattle
grubs. However, proper timing of treatment is important. For
the most effective results, cattle should be treated as soon as
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While this is not peculiar to ivermectin, destruction of
Hypoderma larvae (cattle grubs) at the period when these
grubs are in vital areas may cause undostrable host-parasite
reactions. Killing Hypoderma lineatum when it is in the
esophageal tissues may cause bloat; killing H. bovis when it
is in the vertebral canal may cause staggering or paralysis.
Cattle should be treated either before or after these stages of
grub development. arub development.

cattle treated with IVOMEC Pour-On at the end of the fly season may be re-treated with IVOMEC during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

Environmental Safety

Environmental Safety
Studies indicate that when ivermectin comes in contact with
soil it readily and tightly binds to the soil and becomes
inactive over time. Free ivermectin may adversely affect fish
and certain aquatic organisms. Do not permit cattle to enter
lakes, streams or ponds for at least six hours after treatment.
Do not contaminate water by direct application or by
improper disposal of drug containers. Dispose of containers
in an approved landfill or by incineration.

in an approved anomin or by incineration.

As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-

HOW SUPPLIED

IVOMEC Pour-On is available in an 8.5 fl oz/250 mL bottle or 33.8 ft oz/1 L bottle with a squeeze-measure-pour system, or in an 84.5 ft oz/2.5 L or 169 oz/5 L collapsible pack, or 676 ft oz/20 L. container intended for use with appropriate automatic dosing equipment.

Merial Limited 3239 Satellite Bivd. Duluth, Georgia 30096-4640, U.S.A.

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Merial Limited, a company limited by shares registered in England and Wales (registered number 3332751) with a registered office at PO Box 327, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex CM19 STG, England, and domesticated in Delaware, USA as Merial LLC.

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Made in U.S.A. Rev. 08-2003



Page 7

Page 8

Leaflet Front Pg. 1

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Page 4

Page 3

Page 2

Set the dose by turning the top section of the cup to align the connect body weight with the pointer on the founded cap. When body weight is between markings, use the higher

Squeeze-Measure-Pour System (33.8 if ozil Line Bottle with 50 mL Metering Cup) Attach the metering cup to the bottle.

By releasing the pressure, the dose automatically adjusts to the correct-level. This the bottle ib deliver the dose. The off (STOP) position will close the system between dosing.

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Set the dose by turning the top section of the cup to align the contect body weight with the pointer on the forusted cap. Wheen body weight with the pointer on the ingher souther.

Attach the metering cup to the bottle. Squeeze-Measure-Pour System (8.5 fl oz/250 mL Bottle with 25 mL Metering Cup) NOTTARTZINIMGA

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Treatment of Cattle for Horn Files

NOMEC Pour-On controls horn files (Haematobia knitans)
NOMEC Pour-On controls horn files (Haematobia Nomeron Pour-On Pour-On should be part of a parasite control program for both internal and external perasites based on the epidemiology of the set in the program for the more statement of a parasite control pour set in the program of the progra

Trichostrongylus axel for 21 days after treatment, Ostanagia ostanagi, Haemonchus placel, Coopena cumabada for 14 days after treatment; Damainia bovs for 56 days after treatment.

Oesophagostomum radiatum and Dichocaulus viviparus for 28 days after treatment; Coopena punctata and Persistent Activity has been proved to effectively control infections and to protect cattle from re-infection with:

anatini sidotamesi Hom Files Solenopotes capitlatus

Damalinia bovis sumetaytus aurigotemesh ILUTA SUMBERGOOM 8017

Sarcoptes scabiel var. bovis SOUM

Hypoderma bovis H. lineatum (benseinc arades) cattle Grubs (adults and L4) Dictyocaulus viviparus LUCAROUNS Indhuris spp. (adults) adults) Susopides papiliosus Oesopyagosiounu maliatum (a) bns stlube) bns stlube) bns stlube) bns stlube) bns stlube) (stlube) Coopena sumabada Cooperia punctata Coopenia oncophora Castrointsetinal Roundworms Castragia casaragia (Including inhibited stage) Haemonotus pacei Inchostrongylus axei I. Coklotiforms (by pue stiube)

MUNCATIONS (ivermectin) Pour-On applied at the recommended dose level of 500 mog/kg is indicated for the recommended dose level of 500 mog/kg is indicated for the recommended dose level of 500 mog/kg. realment and control of these parasites

readily cross the blood brain barrier. to the tax that manneds do not have glutamate-gated chloride of the tax of the control of the co The margin of safety for compounds of this class is attributable

neuronansmitter gamma-aminobulyric acid (GABA). disted chloride channels, such as those gated by the Compounds of this class may also interact with other ligandmuscle cell, resulting in paralysis and death of the parasite. membrane to chloride lons with hyperpolarization of the nerve or This leads to an increase in the permeability of the cell and muscle ceits.

endeclocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamete- of the chart bind charter which occur in invertebrate nerve ivermectin is a member of the macrocytic lactone class of MODE OF ACTION

chemical entity. Laboratories, IVOMEC Pour-On contains ivermectin, a unique Discovered and developed by scientists from Merck Research parasite control in one convenient low-volume application, IVOMEC (ivermedin) Pour-On delivers internal and external NOTTO DUCTION

treatment and control of parasitism. Consult your veterinarian for assistance in the diagnosis, bonk-on 🗠 🖦

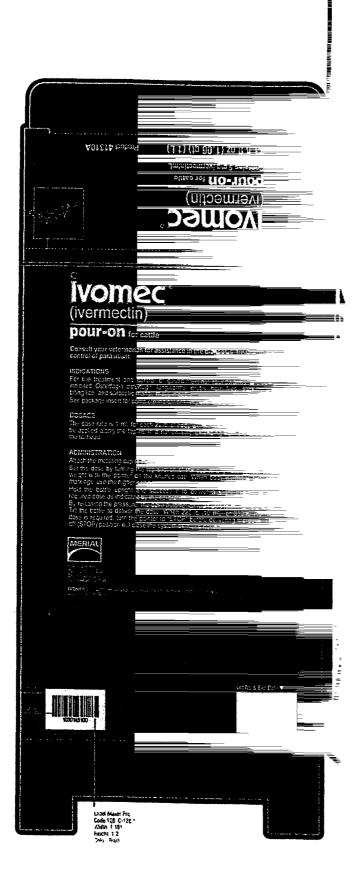
> (ivermectin)

2 3/8"

2 3/8"

2/1/2"

Inside



VOMPC (1/10 FT)

(iVermectin)

pour-on for callo contains 5 mg ivermectining

contains 5 mg ivermectining

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Congression. 1030-1451-00

Ivomec (ivermectin)

pour-on for cattle

Animal Safety

Studies conducted in the U.S.A. have definings rated the safety margin for invertigation. Based or plasmaterists the topically as proceedings with the safety metallic in expected to be or least as well to stand or by treat or altimates as it the subclame as formulation which had no effect or transcription.

WARNING NOT FOR USE IN HUMANS. Keep this and all drings out of the reach of chadren

WARNING FLAMMABLE KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES

RESIDUE INFORMATION.
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Rev 64-2003 1023-1401-23



pour-on for cattle

Contains 5 mg ivermectin/m

Parasiticide

MERIAL GLOBAL PACKAGING TECHNOLOGY

Kills: Roundwarms (including Brown Stamach L Lungwarms, Grubs, Suching Lice, Blung Lee Mange Mitts, Horn Flee

Contains 40-550 lb bases

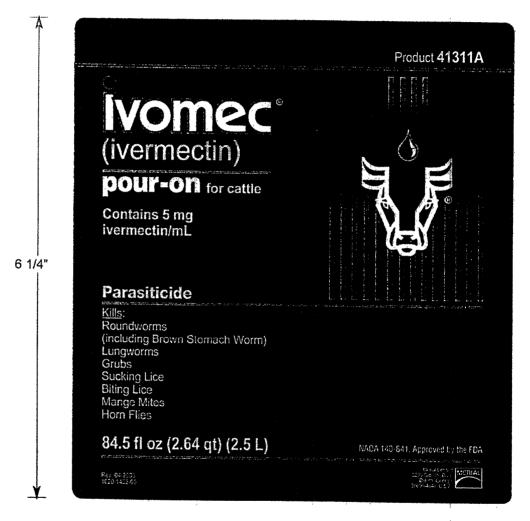


33.8 fl oz (1.05 ql) (1

Let No & Exp Date ♥

1023-1461-2





Cyan does NOT Print

V

MERIAL GLOBAL PACK	AGING TECHNOLOGY	Component # 1020-1453-00
Client: Ruminent Animal Global Enterprise Originator: Tanyja Porcha Country: USA Brand: Ivomec Pour-On Project: 2.5 Liter Component Description: Label - Front	Graphic Designer: Chandra Bulmer Telephone #: 678-638-3261 Date: 13 June 2003 Revision - Date: A - 03/07/03 Note: this revision B - 04/04/03 history is for Internal C - 04/15/03 PRD GPT purposes ONLY D - 06/13/03 Revised PRD	Colors: Use PANTONE MATCHING SYSTEM for an accurate color representation. PMS 874 Gold Special Brown (c=0/m=74/y=100/k=80) Magenta Yellow Mertal Limited 3229 Santing bod. MERIAL Outun, 84 30094 U.S. A.

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. INDICATIONS

For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

Recommended Dose: 1 mL per 22 lb of body weight.

WARNING

NOT FOR USE IN HUMANS. Keep this and all drugs out of the reach of children.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Merial at 1-888-637-4251.

WARNING! FLAMMABLE!

KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

RESIDUE INFORMATION: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for yeal.

6 1/4"

PRECAUTIONS

Store away from excessive heat (104°F/40°C) and protect from light.

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to well cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVOMEC® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

Lot No & Exp Date ▼

U.S. Pat. 4,199,569

Made in U.S.A.

IVOMEC and Cattle Head Logo are registered trademarks of Merial Limited.

Unvarnished Area 1-1/2"W x 1"H

84.5 fl oz (2.64 qt) (2.5 L)

Rev. 04-2003 1020-1454-00

Cyan does NOT Print

IVIERIAL GLOBAL PACKAGING TECHNOLOGY

Graphic Designer: Chandra Bulmer Telephone #: 678-638-3261

Note: this revision history is for internal B - 03/26/03 C - 04/15/03 PRD

Colors:

Use PANTONE MATCHING SYSTEM for an accurate color representation.

Component #

Special Brown (c=0/m=74/y=100/k=80 PMS 185 Red

1020-1454-00

3239 Satellite Blvd.

Client: Ruminent Animal Global Enterprise Originator: Tanyja Porcha Country: USA Brand: Ivomec Pour-On Project: 2.5 Liter Component Description: Label - Back

Date: 15 April 2003 Revision - Date: A-03/07/03

GPT purposes ONLY

IVOMEC (ivermectin)

pour-on for cattle

Contains 5 mg ivermectin/mL

Product 41311A

84.5 fl oz (2.64 qt) (2.5 L)

Product 41311A

IVOMEC (ivermectin)

pour-on for cattle

Contains 5 mg ivermectin/mL

Parasiticide

Kills: Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies

Contains 100-550 lb Doses





84.5 fl oz (2.64 qt) (2.5 L)



IVOMec (ivermectin)

pour-on for cattle

This topically applied formulation of WOMEO's (ivermedial) dislives internal and external parasite control in one convenient low-volume application. PRECAUTIONS

Store away from excessive hea (104°F/40°C) and protect contents from light.

Use only in well-ventilated areas outdoors,

Close container lightly when not in use. Cattle should not be treated when hair a hide is wall since reduced efficacy mabe experienced.

Do not use when rain is expected to we

This product is for application to skir surface only. Bo not give orally or parenterally

Cloudiness in the formulation may accument IVOMEC Pour-On is stored a temperatures below 32°F. Allowin to warm at room temperature wirestor the normal appearance without affecting efficacy.

Antiphrasitic activity of wormed in will be impaired if the formulation is amplied to areas of the skin with mannes scales or set tesions, or with dermatoses or adi erent materials. Fig. ciked multiphanical

Ivermeetin has been associated with adverse reactions in sensitive day therefore. IVOMEC Pour On its na recommended for use in species of than cattle.

Do not contaminate water by direct application or by the improper disposal of diag containers. Dispose of containers an approper disposal for the improper of the analysis of the improper of



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Cyan does NOT Print!

MERIAL GLOBAL PACKAGING TECHNOLOGY Compensary, 1030-1455-00 Colors: Lan Platford: La (Caraci, 5) 5 Tital for An Activities La (Caraci, 5) 5 Tital for An Activities Land recoverage on Special Brown (Culy 2x-7 L/y-1 (Calu-Si)) Black Langesta Vellow Landel Linear (Caraci) Vellow Landel Linear (Caraci) Landel Linear (Caraci) Linear Telephone # 678-638-3261 Date 13 June 2003 Yanvia Porcha Country USA Brand Ivernec Pour-On Project: 2.5 Liter

Ivomec (ivermectin)

DOUR-On for cattle

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

For the treatment and control of gastrointestinal round.coms (including inhibited Ostertagia ostertagia), lungworms, grubs, horn files, sucking and biting fice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions

DOSAGE

The dose rate is 1 mt, for each 22 ib of body weight. The formulation should be applied along the topline in a narrow stop extending from the withers to the tailhead.

ADMINISTRATION

Connect the applicator gun to the collapsible pack as follows:

Connect the applicator gain to the congression pack as topows.

Attach the open end of the draw-off thong to the desing equipment (Because of the solvents used in the formulation only the Protector Brench Cain from Instrument. Supplies Limited or equivalent is recommended. Other applicators may exhibit compatibility problems, resulting in tecking incorrect dosage or leakage.)

Replace the shipping cap with the draw-off cap and tighten draw. Attach draw-off tubing to the draw-off cap

Gently prime the applicator gun, checking for leaks

Centry prime the applicant growth decking for radyshing the dose.

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw off tubing from the product container and empty, the product from the gun and tubing back into the product container. To prevent remained of special lubricants from the Protector Dranch Qun, the gun and tubing must not be washed.







Ivomec (ivermectin)

pour-on for cattle

Animal Safety

Animal Safety
Studies conducted in the U.S.A. have demonstrated the safety margin for wermectin. Based on plasma levels the Lopically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING NOT FOR USE IN HUMANS. Keep this and all drugs out of the reach of children.

This product should not be applied to self or others because it may be introduce to human skin and eyestiance absorbed through the skin. To minimize accidental skin contact to the service of the servic

WARNING! FLAMMABLE! KEEP AWAY FROM HEAT, SPARKS OPEN FLAME, AND OTHER SOURCES OF IGNITION.

RESIDUE INFORMATION RESIDUE INFORMATION: Cattle must not be treated within 48 days of slaughter for human consumption. Because a within drawalt time in mils has not been established, do not use in female darry cattle of breeding age. A withdrawal period has not been established for this product in pre-rumnating calves. Do not use in calves to be processed for veal

vomec (ivermectin)

DOUN-On for cattle

Contains 5 mg ivermeetin/mL

84.5 ft oz (2.64 gt) (2.5 L)

Product 4131fa-

Product 413117

ivome (ivermectin)

pour-on for cattle

Contains 5 mg ivermectin/mL

Parasiticide

Kills: Roundworms (including Brown Stomach Works, Sucking Lice, Biting Brown Mange Mites, Horn Flies

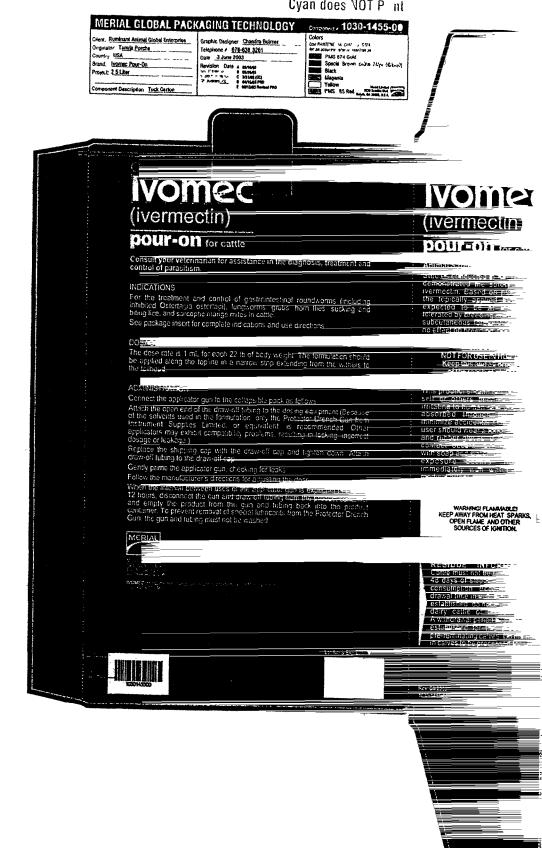
Contains 100-550 lb Doses





84.5 fl oz (2.64 qt) (2.5 L)

Cyan does VOTP nt



Dieline for Merial 5L Front and Back Labels Final Label size is 8" x 9" Created 12/02

Cyan does NOT Print

MERIAL GLOBAL PACK Client: Ruminent Animal Global Enterprise	AGING TECHNOLOGY Graphic Designer: Chandra Bulmer	Companies = 1020-1457-00 Colors: Use PANTONE MATCHING SYSTEM
Originator: Tanyia Porcha Country: USA Brand: Ivomec Pour-On Project: 5 L	Telephone #: 678-638-3261 Date: 13 June 2003 Revision - Date: A - cserzos Mais files revision - 6 - col/scos PRD Pi proposo (MY) - 0 - 601500 PRD Pi proposo (MY) - 0 - 601500 PRD	for an accurate color representation. PMS 874 Gold Special Brown (c=0/m=74y=100/k=80) Magenta Yellow
Component Description: Label (front)		Delat Limited Programs 2229 Seattle Bird. Delan, GA 30096, U.S.A.

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

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See package insert for complete indications and use directions.

Recommended Dose: 1 mL per 22 lb of body weight.

WARNING NOT FOR USE IN HUMANS.

Keep this and all drugs out of the reach of children.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Merial at 1-888-637-4251.

WARNING! FLAMMABLE! KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

RESIDUE INFORMATION: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for year.



× .

9"

Store away from excessive heat (104°F/40°C) and protect from light.

Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVOMEC® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

hvermectin has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

U.S. Pat. 4,199,569

Made in U.S.A.

IVOMEC and Cattle Head Logo are registered trademarks of Merial Limited.

Lot No & Exp Date V

Unvamished Area 1-1/2"W x 1"H

169 fl oz (5 L)

Rev. 04-2003

Dieline for Merial 5L Front and Back Labels Final Label size is 8" x 9" Created 12/02

Cyan does NOT print.

MERIAL GLOBAL PACK	AGING TECHNOLOGY	Component # 1020-1458-00
Client: Ruminent Animal Global Enterprise Originator: Tamyla Porcha Country: USA Brand: Nomec Pour-On Project: 5 L Component Description. Label (back)	Graphic Designer: Chandra Bulmer Telephone #: 678-638-3261 Date: 15 April 2003 Revision - Date: A - corornos fice: the report 5 - carzenos Instry is for retural C - 64/15/03 PRD GP/ remose (PRY)	Colors: Use PARTCHINE MATCHING SYSTEM for an accurate color representation. Special Brown (c-0/m=74/y=100/k=80 PMS 185 Red Special Emistre (c-0/m=74/y=100/k=80) PMS 185 Red

Cyan does NOT Print!



Product 41350A

Ivomec (ivermectin)

pour-on for cattle

Contains 5 mg ivermectin/mL

Parasiticide

Kills: Roundworms (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies

Contains 200-550 lb Doses





169 fl oz (5 L)

MERIAL

ivomec (ivermectin)

pour-on for cattle

This topically applied formulation of WONEO's (nermedian between internal an external parasite conto-in one convenier low-volume application.)

PRECAUTIONS
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Use any in well-vents are as an outdoor

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This product is for application to skin surface only. On not now good, or least revenue.

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Do not contaminate victs: by direct age toation or by the improper distracts or discount newspapers and agent with a section.



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(7 g) zo || 69 L

Contains 5 mg ivermectin/ml. Donk-On tor cottle (ivermectin) NOWSC

Cyan does NOT Print

Product 41350/

omec rmectin)

Ir-on for cattle

r veterinarian for assistance in the diagnosis, treatment and control of parasitism.

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ivomeç (ivermectin)

pour-on for cattle

Animal Safety

lvome

(ivermectin)

pour-on for cattle

Contains 5 mg ivermectin/mL

Parasiticide

Kills: Roundworms (including Brown Stomach Worm Lungworms, Grubs, Sucking Lice, Biting Lic Mange Mites, Horn Flies

Contains 200-550 lb Doses

169 fi oz (5 L)

Product 41350A (7 g) zo | 69 Jminiosmievi gm 2 anistae SOUR-OR for callle VOMSC vermectin)

IVOMec (ivermectin)

pour-on for cattle

Consult your veterinarian for assistance in the diagnosis, treatment and control

For the theatment and control of gastrontesting counteworms (including and osterlag) (lungworms grubs from fices sucking and thing fice and salpsus mang. See pickings insert for complete indications and use directions.

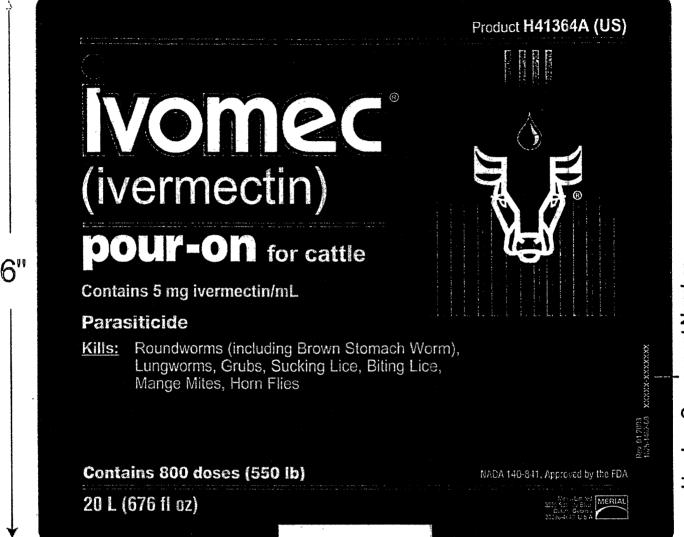
The date rate is 1 mL for cach 22 its of body weight. The formulation should be coping in a namew stup extending from the witness to this 13 hyad.

ADMINISTRATION

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Haarlem to insert GMP Barcode Here

Note: Cyan does NOT Print

1025-1462-00 **GLOBAL PACKAGING TECHNOLOGY** Component # Client: Ruminent Animal Global Enterprise Graphic Designer: Chandra Bulmer Use PANTONE MATCHING SYSTEM Originator: Tanyja Porcha for an accurate color representation. Telephone #: 678-638-3261 PMS 874 Gold Date: 13 June 2003 Country: USA Special Brown (c=0/m=74/y=100/k=80) Brand: Ivomec Pour-On Revision - Date: A - 03/10/03 Magenta Note: this revision B - 03/25/03 Project: 20 Liter Yellow history is for internal C - 04/15/03 PRD GPT purposes ONLY D - 06/13/03 Revised PRD Component Description: Shipper Label - Front

Note: Cyan does NOT print.

Product H41364A (US)

(ivermectin)

pour-on for cattle

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

For the treatment and control of gastrointestinal roundworms (including inhibited Osteragia osteriagi), tungworms, grubs, hom files, sucking and biting lice, and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

DOSAGE

61/8''

The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead **ADMINISTRATION**

Use dosing equipment (applicator, draw-off tubing, cap with stem) compatible with IVOMEC® (ivermectin) Pour-On. Other dosing equipment may be incompatible. resulting in locking, incorrect dosage and leakage. Follow the dosing equipment manufacturer's directions for adjusting the dose and proper use and maintenance of the dosing equipment. Connect the dosing applicator and the draw-off tubing to the container as follows:

Attach the open end of the draw-off tubing to an appropriate dosing applicator. Attach draw-off tubing to the cap with the stem. Replace the shipping cap with the cap having the draw-off tubing. Gently prime the dosing applicator, checking for leaks.

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun, draw-off tubing and cap with stem from the product container, empty the product from the gun and tubing back into the product container and replace the shipping cap.

Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING NOT FOR USE IN HUMANS Keep this and all drugs out of the reach of children.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Merial at 1-888-637-4251.

> WARNING! FLAMMAR! FI KEEP AWAY FROM HEAT. SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION

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RESIDUE INFORMATION: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for year.

Store away from excessive heat (104°F/40°C) and protect from light. Use only in well-ventilated areas or outdoors.

Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be

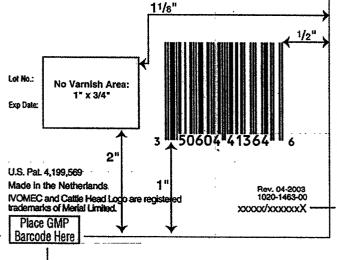
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fermedin has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in species other than cattle.

Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.



Haarlem to insert **GMP Barcode Here**

MERIAL GLOBAL PACKAGING TECHNOLOGY

Client: Ruminent Animal Global Enterprise

Graphic Designer: Chandra Bulmer

Telephone #: 678-638-3261

Date: 15 April 2003

Note: this revision

B - 03/26/03

history is for internal GPT purposes ONLY

Component Description: Shipper Label - Back

Originator: Tanyja Porcha

Brand: Ivomec Pour-On

Project: 20 Liter (Merialization)

Country: USA

Revision - Date: A - 03/07/03

C - 04/15/03 PRD

Merial Limited MERIAL 3239 Satellite Blvd. Duluth, GA 30096, U.S.A.

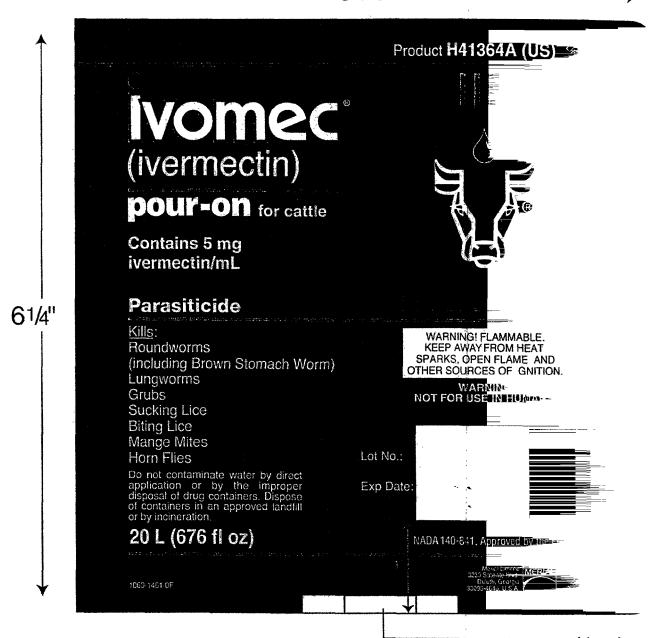
Haarlem Component Number (to be added by Haarlem)

Use PANTONE MATCHING SYSTEM for an accurate color representation.



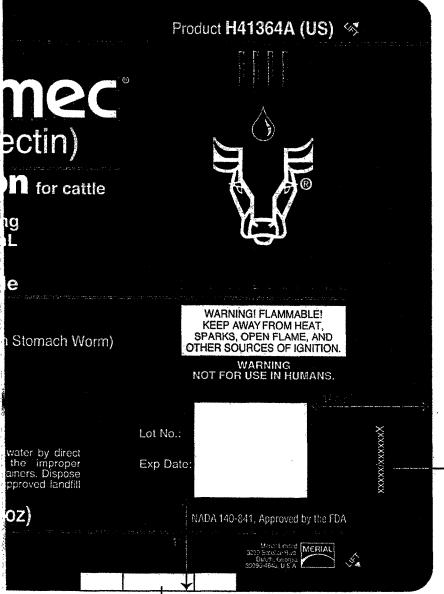
Special Brown (c=0/m=74/v=100/k=80) PMS 185 (red)

Component # 1020-1463-00



Outsert Front Cover

Haarlem GMP Bar



MERIAL GLOBAL PACKAGING

Client: Ruminant Animal Global Enterprise Originator: Bruce Somerville Country: USA Brand: Ivomec Pour-On

Project: 20 Liter (Revise Persistent Activity)

Component Description: Outsert

Telephone #: Date: 18 Aug

Graphic Desig

Revision - Dat Note: this revision history is for internal GPT purposes ONLY

Haarlem-Component Number

tsert Front Cover

Haarlem to insert GMP Barcode Here

PMS 874 Gold

Black

Yellow

Magenta

1020-1461-0F

Merial Limited 3239 Satellite Blvd. Duluth, GA 30096, U.S.A.

Special Brown (c=0/m=74/y=100/k=80)

MERIAL GLOBAL PACKAGING TECHNOLOGY Component # Colors: Client: Ruminant Animal Global Enterprise Graphic Designer: Patricia Greene Use PANTONE MATCHING SYSTEM for an accurate color representation. Originator: Bruce Somerville Telephone #: 678-638-3302 Date: 18 August 2003 Country: USA Brand: Ivomec Pour-On Revision - Date: A - 03/28/03 Note: this revision B - 03/28/03 (SM) Project: 20 Liter (Revise Persistent Activity) history is for internal C - 08/18/03 (PG) GPT purposes ONLY Component Description: Outsert

sert Here



pour-on for cattle

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

INTRODUCTION

IVOMEC (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application. Discovered and developed by scientists from Merck Research Laboratories, IVOMEC Pour-On contains ivermectin, a unique chemical entity.

MODE OF ACTION

Ivermectin is a member of the macrocylic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells.

This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligandgated chloride channels and they do not readily cross the blood-brain barrier.

IVOMEC Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the treatment and control of these parasites.

Gastrointestinal Roundworms

Ostertagia ostertagi (including inhibited stage) Haemonchus placei

Trichostrongylus axei T. colubriformis

(adults and La)

(adults and L_4) adults and La (adults and La)

Cooperia oncophora Cooperia punctata Cooperia sumabada Strongyloides papillosus Oesophagostomum radiatum Trichuris spp.

Lungworms Dictyocaulus viviparus

Cattle Grubs Hypoderma bovis H. lineatum

Mites

Sarcoptes scabiei var. bovis

Lice Linognathus vituli Haematopinus eurysternus Damalinia bovis Solenopotes capillatus

Horn Flies Haematobia irritans

Persistent Activity

IVOMEC Pour-On has been proved to effectively control infections and to protect cattle from reinfection with: Oesophagostomum radiatum and Dictyocaulus viviparus for 28 days after treatment; Cooperia punctata and Trichostrongylus axei for 21 days after treatment; Ostertagia ostertagi, Haemonchus placei, Cooperia oncophora and Cooperia sumabada for 14 days after treatment; Damalinia bovis for 56 days after treatment.

Treatment of Cattle for Horn Flies

IVOMEC Pour-On controls horn flies (Haematobia irritans) for up to 28 days after dosing. For best results IVOMEC Pour-On should be part of a parasite control program for both internal and external parasites based on the epidemiology of these parasites. Consult your veterinarian or an entomologist for the most effective timing of applications.

DOSAGE

The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline in a narrow strip extending from the withers to the tailhead.

ADMINISTRATION

Squeeze-Measure-Pour System (8.5 fl oz/250 mL Bottle with 25 mL Metering Cup) Attach the metering cup to the bottle.

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(adults and L₄) (parasitic stages)

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Gun from Instrur is recommende compatibility prodosage or leaka Replace the ship tighten down. At cap.

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Outsert Page 1 (inside front cover)

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an for assistance in the control of parasitism.

ir-On delivers internal and one convenient low-volume ad developed by scientists pratories, IVOMEC Pour-On e chemical entity.

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the permeability of the cell with hyperpolarization of the ng in paralysis and death of this class may also interact ide channels, such as those or gamma-aminobutyric acid

compounds of this class is at mammals do not have channels, the macrocyclic for other mammalian ligandd they do not readily cross

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Lungworms Dictyocaulus viviparus

Cattle Grubs Hypoderma bovis H. lineatum

Mites

Sarcoptes scablel var. bovis

Lice

Linognathus vituli Haematopinus eurystemus Damalinia bovis Solenopotes capillatus

Horn Flies

Haematobia irritans

Persistent Activity

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ADMINISTRATION

Squeeze-Measure-Pour System (8.5 fl oz/250 mL Bottle with 25 mL Metering Cup)

Attach the metering cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. The off (STOP) position will close the system between dosing.

Squeeze-Measure-Pour System (33.8 fl oz/1 Liter Bottle with 50 mL Metering Cup)

Attach the metering cup to the bottle.

Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. When 220 to (10 mL) or 330 to (15 mL) dose is required, turn the pointer to "STOP" before delivering the dose. The off (STOP) position will close the system between dosing.

Collapsible Pack (84.5 fl oz/2.5 L Pack and 169 fl oz/5 L Pack)

Connect the applicator gun to the collapsible pack

Attach the open end of the draw-off tubing to the dosing equipment. (Because of the solvents used in the formulation, only the Protector Drench Gun from Instrument Supplies Limited, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage.)

Replace the shipping cap with the draw-off cap and tighten down. Attach draw-off tubing to the draw-off cap.

Gently prime the applicator gun, checking for leaks. Follow the manufacturer's directions for adjusting the dose.

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw-off tubing from the product container and

empty the product from the gur the product container. To prew lubricants from the Protector I and tubing must not be washed 20 Liter Pack

(676 fl oz/20 L Pack)

Use dosing equipment (applicate with stem) compatible with 1\text{Pour-On. Other dosing e incompatible, resulting in lock and leakage. Follow the manufacturer's directions for a proper use and maintenance of Connect the dosing applicator a to the container as follows:

Attach the open end of the cappropriate dosing applicat tubing to the cap with the shipping cap with the cap tubing. Gently prime the checking for leaks.

When the interval between us gun is expected to exceed 12 I gun, draw-off tubing and cap product container, empty the r and tubing back into the proreplace the shipping cap.

ANIMAL SAFETY

Studies conducted in the U.S.A the safety margin for ivermecti levels, the topically applied form be at least as well-tolerated by is the subcutaneous formulation on breeding performance.

WARNING NOT FOR USE IN I Keep this and all drugs out of t

The Material Safety Data Sheet (detailed occupational safety informatificats, obtain an MSDS or for ass at 1-888-637-4251.

WARNING! FLAM KEEP AWAY FROM HEAT, SPA AND OTHER SOURCES

This product should not be app because it may be irritating to h and absorbed through the

Outsert Page 1 inside front cover)

Outsert Page 2

Facsimile Labeling

57/16"

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pressure, the dose automatically rect level. Tilt the bottle to deliver the IOP) position will close the system

ve-Pour System • Bottle with 50 mL Metering Cup) ing cup to the bottle.

urning the top section of the cup to body weight with the pointer on the n body weight is between markings, time

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pressure, the dose automatically ect level. Tilt the bottle to deliver the b (10 mL) or 330 lb (15 mL) dose is pointer to "STOP" before delivering if (STOP) position will close the using.

Pack and 169 fl oz/5 L Pack) ---- licator gun to the collapsible pack

end of the draw-off tubing to ment. (Because of the solvents ulation, only the Protector Drench ent Supplies Limited, or equivalent, Li Other applicators may exhibit lems resulting in locking, incorrect a.)

oing cap with the draw-off cap and ach draw-off tubing to the draw-off

applicator gun, checking for leaks. Leturer's directions for adjusting the

between uses of the applicator gun seed 12 hours, disconnect the gun ig from the product container and empty the product from the gun and tubing back into the product container. To prevent removal of special lubricants from the Protector Drench Gun, the gun and tubing must not be washed.

20 Liter Pack (676 fl oz/20 L Pack)

Use dosing equipment (applicator, draw-off tubing, cap with stem) compatible with IVOMEC® (ivermectin) Pour-On. Other dosing equipment may be incompatible, resulting in locking, incorrect dosage and leakage. Follow the dosing equipment manufacturer's directions for adjusting the dose and proper use and maintenance of the dosing equipment. Connect the dosing applicator and the draw-off tubing to the container as follows:

Attach the open end of the draw-off tubing to an appropriate dosing applicator. Attach draw-off tubing to the cap with the stem. Replace the shipping cap with the cap having the draw-off tubing. Gently prime the dosing applicator, checking for leaks.

When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun, draw-off tubing and cap with stem from the product container, empty the product from the gun and tubing back into the product container and replace the shipping cap.

ANIMAL SAFETY

Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING NOT FOR USE IN HUMANS. Keep this and all drugs out of the reach of children.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Merial at 1-888-637-4251.

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This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize

Outsert Page 2

Haarlem Component Number (to be added by Haarlem)

Outsert Base

Facsimile Labeling

63/4" 5/16" 1 1/16" 51/8" Killing Hypoderma lineatum when it is in the esophageal tissues may cause bloat; killing H. bovis when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development. Cattle treated with IVOMEC Pour-On at the end of the ty season may be re-treated with IVOMEC during the winter without danger of grub-related reactions. For turther information and advice on a planned parasite control program, consult your veterinarian. **Environmental Safety** Studies indicate that when ivermectin comes in ivermectin contact with soil it readily and tightly binds to the No Print/Glue Area 11/16" w x 61/4" soil and becomes inactive over time. Free 61/4" ivermectin may adversely affect fish and certain OUI'-Of for cattle aquatic organisms. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by improper disposal of drug ≥ Contains 5 mg containers. Dispose of containers in an 5/16" approved landfill or by incineration. ivermectinum As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for Area 61/4" reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent Parasificion Print/GI WAR **HOW SUPPLIED** Roundworms KEEF IVOMEC Pour-On is available in an 8.5 fl oz/250 mL (including Brown Stomach Worm) **SPARK** bottle or 33.8 fl oz/1 L bottle with a soueeze-measure-Lungworms OTHER S pour system, or in an 84.5 fl oz/2.5 L or 169 oz/5 L collapsible pack, or 676 fl oz/20 L container intended for Guine use with appropriate automatic dosing equipment. Sucking Lice IVOMEC and Cattle Head Logo are registered trademarks of Merial Limited. Biting Lice Mange Mites Merial Limited 3239 Satellite Blvd. Duluth, Georgia Horn Flies 1640, U.S.A. Merial Limited, a company limited by shares registered in England and Wates (registered number 3332751) with a registered office at PO Box 327, Sandringham House, Sandringham Avenue, Harlow Business Parit, Harlow, Essex CAH19 51G, England, and domesticated in Delaware, USA as Merial LLC. 20 L (676 fl oz U.S. Pat 4,199,569 Copyright © 2003 Merial Limited All Rights Reserved. Made in the Netherlands Rev. 08-2003

k of Page 2

Outsert Base

accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

RESIDUE INFORMATION: Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PRECAUTIONS

Store away from excessive heat (104°F/40°C) and protect from light.

Use only in well-ventilated areas or outdoors. Close container tightly when not in use.

Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.

Do not use when rain is expected to wet cattle within six hours after treatment.

This product is for application to skin surface only. Do not give orally or parenterally.

Cloudiness in the formulation may occur when IVOMEC® (ivermectin) Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or tesions, or with dermatoses or adherent materials, e.g., caked mud or manure.

Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVOMEC Pour-On is not recommended for use in species other than

When to Treat Cattle with Grubs IVOMEC Pour-On effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For the most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season. While this is not peculiar to ivermectin, destruction of Hypoderma larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions.

Killing Hypoderma lineatum when it is in the esophageal tissues may cause bloat; killing H. bovis when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development.

Cattle treated with IVOMEC Pour-On at the end of the fly season may be re-treated with IVOMEC during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

Environmental Safety

Studies indicate that when ivermectin comes in contact with soil it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish and certain aquatic organisms. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent

HOW SUPPLIED

IVOMEC Pour-On is available in an 8.5 fl oz/250 mL bottle or 33.8 fl oz/1 L bottle with a squeeze-measurepour system, or in an 84.5 fl oz/2.5 L or 169 oz/5 L collapsible pack, or 676 fl oz/20 L container intended for use with appropriate automatic dosing equipment.

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Merial Limited 3239 Satellite Blvd. Duluth, Georgia 30096-4640, U.S.A.

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